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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,292	08/14/2006	Benny Bang-Andersen	463USPCT	3519

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EXAMINER	
BERNHARDT, EMILY B	

ART UNIT	PAPER NUMBER
1624	

MAIL DATE	DELIVERY MODE
02/03/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/568,292	BANG-ANDERSEN ET AL.	
	Examiner	Art Unit	
	EMILY BERNHARDT	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 November 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *34-44,47,50 and 51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *34-44,47,50 and 51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/21/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

In view of applicants' response filed on 11/13/08 the following still applies.

Claims 34, 36 and 47 are objected to because of the following informalities: In claim 34 as now amended "a name" would better read as "the name". Claims 36 and 47 are substantial duplicates. Appropriate correction is required.

Claims 50 and 51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The narrower scope covered in new claims 50 and 51 is not seen to be described in the disclosure as originally filed.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 34 remains rejected under 35 U.S.C. 102(b) as being anticipated by Bogeso (J.Med. Chem.). In the absence of a purity limitation the instantly recited enantiomer reads on the racemic mixture which was necessarily used to prepare corresponding N-Me derivatives as shown in the reaction scheme (Scheme 1). No other synthesis was relied on. Note In re Adamson cited previously which is on point.

Claims 34-44,47 and 50-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bogeso (J.Med. Chem) in view of EP Bogeso for reasons of record. New claims 50 and 51 are also rejected herein since EP Bogeso also teaches treating

depression without qualification as to its source. It is not agreed that the combination rejection fails to render instant trans enantiomer obvious for the uses taught by Bogeso. A very recent decision regarding the patentability of a stereoisomer over the corresponding racemate is on point. See Aventis Pharma Deutschland Gmbh v. Lupin Ltd. 84 USPQ2d 1197 especially at 1204: "The "reason or motivation" need not be an explicit teaching that the claimed compound will have a particular utility; it is sufficient to show that the claimed and prior art compounds possess a "sufficiently close relationship … to create an expectation," in light of the totality of the prior art, that the new compound will have "similar properties" to the old. *Dillon*, 919 F.2d at 692; *see also In re Wilder*, 563 F.2d 457, 460 [195 USPQ 426] (C.C.P.A. 1977) ("[O]ne who claims a compound, per se, which is structurally similar to a prior art compound must rebut the presumed expectation that the structurally similar compounds have similar properties."). Once such a prima facie case is established, it falls to the applicant or patentee to rebut it, for example with a showing that the claimed compound has unexpected properties. *Dillon*, 919 F.2d at 692. This is exactly the case herein. While Bogeso ,the reference, only employs the racemate as a precursor, it is taught as interchangeable with the final products (**38** and resolved forms**)** it ultimately makes by EP Bogeso. In Bogeso, the reference, the isomers having the 1R,3S configuration are particularly singled out as having the desired activity worth investigating. See p.4382, right column. There is no "teach away" as applicants urge. While compound **41** is fluorinated, **38** is not and both are taught to be active as D1/D2 and as 5-HT2 antagonists. With regard to EP Bogeso there is a clear teaching to resolve each and every **trans** compound as discussed in

section [0021] since EP Bogeso is aware of the desirable mixed antagonist activity that one of a pair will posses. Also R1 as H is within the preferred embodiments when Ar is phenyl. See section [0025]. The recent Supreme Court decision (the KSR decision) is not seen to refute the examiner's position. Note the following passage in the decision:

"The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." Slip op. at 12. "When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, . . . the fact that a combination was obvious to try might show that it was obvious under § 103." *Id.* at 17."

The Declaration filed on 11/13/08 by Dr./Mr. Bang-Andersen, one of the co-inventors is acknowledged. While the raw data shows a markedly higher IC50 value for instant isomer over corresponding racemate E as well as over racemate C, declarant does not comment on if or how the test results which were conducted at different times, might affect variability (and thus significance) in test results given that different enzyme sources were likely to have been employed. Also, while reference is made as to the practical advantage of being a weak inhibitor of Cytochrome P450 2D6, it would appear such activity is only useful when instant compound is co-administered with drugs that are metabolized by CYP2D6 yet the claims are not limited to such.

Claims 34-44,47 and 50-51 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims directed to compounds, compositions and uses of copending Application No. 11/816394 for reasons of record.

Claims 34-44,47 and 50-51 are provisionally rejected on the ground of

nonstatutory obviousness-type double patenting as being unpatentable over claims of copending Application No. 11/816403 in view of EP Bogeso ('073) for reasons of record.

Applicants do not traverse these rejections. If the instant case is otherwise in condition for allowance, in accordance with MPEP 804, the provisional rejections will be dropped in the present case and applicants should inform the examiner(s) handling the later-filed cases the existence of the present case.

The IDS of 2/21/08 is being forwarded to applicants. Some of the entries are duplicates of those cited in other IDS statements, and have been crossed out. Cox is still not seen in the file. Applicants point to a copending case as having this reference but it is not readily seen. Note that MPEP 609 requires applicants to point out the pertinent pages. If such is not indicated the reference will not be considered.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Bernhardt whose telephone number is 571-272-0664.

If attempts to reach the examiner by telephone are unsuccessful, the acting supervisor for AU 1624, James O. Wilson can be reached at 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Emily Bernhardt/

Primary Examiner, Art Unit 1624

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